Convaid

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SEP 2 0 2012

Convaid Product Inc.
Model: CHAMP Manual Wheelchair
K120501
510(k) Summary
of
Safety and Efficacy

A. General Information

1.	Submitter Name:	Convaid Products Inc.
2.	Address:	2830 California St. Torrance CA, 90503
3.	Telephone: Fax:	310-618-0111 310-618-2172
4.	Contact Person:	Donald Griggs Quality Assurance Manager
5.	Registration Number:	2022883
6.	Date Prepared:	07/02/2012

B. Device

1.	Device Trade Name:	Champ
2.	Common/Generic Name:	Wheelchair-Manual
3.	Device Classification Name:	Mechanical Wheelchair
4.	Registration Number:	222022883
5.	Product Code:	IOR
6.	Device Classification	Class 1
7.	Regulatory Number:	890.3850

C. Identification of Legally Marketed Devices

1.	Manufacture Name:	Otto Bock
2.	Name:	Bravo Racer
3.	K Number:	K082314
4.	Date Cleared:	10/28/2008

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D. Description of the device

The Champ CH10 and CH10T are lightweight folding aluminum and steel framed wheelchairs with a seating module that can be used with an optional activity base. It contains the same typical components found on most manual wheelchairs.
Champ CH10T transit model is the CH10 model with the addition of transport anchors. The CH10T model has been crash tested to WC- Vol 1 section 19:2000 and approved for use as seating in a motor vehicle.
See section 11 device description for a more detailed description.

E. Intended Use

Convaid's Champ model CH10 is a lightweight non-ridge high strength aluminum and steel manual wheelchair with a tilt and recline mobility system for everyday indoor and outdoor use on flat firm terrain. The Convaid Champ is a self or attendant propelled device, its' intended function and use is to provide mobility to children with physical disabilities who are frequently or permanently non-ambulatory and limited to a sitting position.
In addition the Champ CH10T transit model has been tested and approved for use as seating in a motor vehicle per ANSI WC -vol-1 section19:2000.

F. Technological Characteristics Summary

The Convaid Champ is substantially equivalent to Otto Bock's Bravo Racer cleared on 10/28/2008 on K082314. The wheelchairs are self or attendant propelled manual wheelchairs, the Champ is a non- ridge folding frame with ten inch seat width were as the Bravo Racer has a ridged frame and has the availability of multiple seat widths ranging from eight to fourteen inches. They both have removable seating modules for easy storage or transport and the Champ's seating module can be used with an optional indoor activity base. The frames are made of tubular coated aluminum and or steel and have small caster in the front for steering and maneuverability and large wheels in the back to allow for self propulsion. Both can be used as seating in a motor vehicle per ANSI-RESNA WC Vol1-19:2000

G: Comparison of device characteristics to predicate

This device (Convaid Champ) has similar characteristics, construction and technology as the predicate device Bravo Racer manufactured by Otto Bock. The Bravo Racer has a ridge frame and removable seating for easy storage and transport, the Champ has a non-ridge frame and removable seating module for easy storage and transport. They use similar materials in the frame and components and both use powder coated frames. The operating characteristics and maneuverability are equivalent and recommended for indoor or outdoor use on flat firm terrain.

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H: Non-Clinical Testing

Convaid's Champ manual wheelchair met the applicable performance requirements as specified below;
RESNA WC 1:2009-1
RESNA WC 2:2009–3
RESNA WC 1:2009-5
RESNA WC 1:2009–7
RESNA WC 1:2009–8
RESNA WC 1:2009-15
RESNA WC 1:2009-16
ANSI-RESNA WC Vol 1 section 19:2000, CH10T only
ISO 10993-5
ISO 10993-10

I: Safety:

The Convaid Champ Wheelchair Series is substantially equivalent to the predicated device listed in the 510(k). The technology and construction of the Champ Wheelchair series does not raise any new issues of safety and effectiveness.

J: Conclusion:

The Champ Wheelchair series shares performance features and technology with the predicate device as well as a number of similar devices already legally marketed within the United States. The use of additional predicate devices and historical data was used in the determination of compliance to specific requirements; see the device description section 11 of this document for detailed information. Therefore the Champ Series wheelchairs are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 20 2012

Comvaid Products, Incorporated
% Mr. Donald Griggs
Quality Assurance Manager
2830 California Street
Torrance, California 90503

Re: K120501
Trade/Device Name: Convaid Products Champ
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: August 28, 2012
Received: August 30, 2012

Dear Mr. Griggs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number: K 120501

Device Name: Convaid Products Champ

Indications for Use:
Convaid's Champ model CH10 is a lightweight non-ridge high strength aluminum and steel manual wheelchair with a tilt and recline mobility system for everyday indoor and outdoor use on flat firm terrain. The Convaid Champ is a self or attendant propelled device, its' intended function and use is to provide mobility to children with physical disabilities who are frequently or permanently non-ambulatory and limited to a sitting position.
In addition the Champ CH10T transit model has been tested and approved for use as seating in a motor vehicle when used in conjunction with an approved four-point, strap-type tiedown system per ANSI-RESNA WC-19:2000.

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K120501